

OCT 20 2006

From the INTERNATIONAL BUREAU

TRASKBRITT, P.C. **PCT**

NOTIFICATION CONCERNING
TRANSMITTAL OF COPY OF INTERNATIONAL
PRELIMINARY REPORT ON PATENTABILITY
(CHAPTER I OF THE PATENT COOPERATION
TREATY)
(PCT Rule 44bis.1(c))

To:

BOND, Laurence, B.
Traskbritt
P.O. Box 2550
Salt Lake City, UT 84110
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year)
12 October 2006 (12.10.2006)

Applicant's or agent's file reference
2102-4389PC

IMPORTANT NOTICE

International application No.
PCT/US2004/035411

International filing date (day/month/year)
26 October 2004 (26.10.2004)

Priority date (day/month/year)
27 October 2003 (27.10.2003)

Applicant

EPIMED INTERNATIONAL, INC. et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Athina Nickitas-Etienne

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 2102-4389PC	FOR FURTHER ACTION	See item 4 below
International application No. PCT/US2004/035411	International filing date (<i>day/month/year</i>) 26 October 2004 (26.10.2004)	Priority date (<i>day/month/year</i>) 27 October 2003 (27.10.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant EPIMED INTERNATIONAL, INC.		

1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 <i>bis</i> .1(a).																								
2.	<p>This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.</p>																								
3.	<p>This report contains indications relating to the following items:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 30%;">Box No. I</td> <td style="width: 80%;">Basis of the report</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>	<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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<input type="checkbox"/>	Box No. VIII	Certain observations on the international application																							
4.	The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).																								

<p style="text-align: center;">The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No. +41 22 338 82 70</p>	<p>Date of issuance of this report 03 October 2006 (03.10.2006)</p> <p>Authorized officer Athina Nickitas-Etienne</p> <p>e-mail: pt04@wipo.int</p>
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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
Laurence B. Bond (TraskBritt)
P.O. Box 2550
Salt Lake City, UTah 84110

PCT

REC'D 04 SEP 2006

WIPO

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) **30 AUG 2006**

Applicant's or agent's file reference

2102-4389PC

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US04/35411

International filing date (day/month/year)

26 October 2004 (26.10.2004)

Priority date (day/month/year)

27 October 2003 (27.10.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC: **A61M 5/178**(2006.01);**A61M 5/32**(2006.01);**A61M 25/00**(2006.01)

USPC: 604/164.01,164.04,168.01,174,180,284

Applicant

EPIMED INTERNATIONAL, INC

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (571) 273-3201

Date of completion of this opinion

05 July 2006 (05.07.2006)

Authorized officer

LoAn H. Thanh

Telephone No. 571 272 4966

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US04/35411

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/35411

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>5,7,10-11,13,19,21-22,26</u>	YES
	Claims <u>1-4,8-9,12,14-18,20,23-25</u>	NO
Inventive step (IS)	Claims <u>6,10,11,13 and 19</u>	YES
	Claims <u>1-5,7-9,12, 14-18, 20-26</u>	NO
Industrial applicability (IA)	Claims <u>1-26</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Please See Continuation Sheet

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/35411

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

V. 2. Citations and Explanations:

Claims 1-4,8-9,12, 14-18,20,23-25 lack novelty under PCT Article 33(2) as being anticipated by Zohmann (US 6,558,353).

Zohmann discloses a spinal catheter assembly having a needle 50 and a spinal catheter 70 wherein the needle 50 has a non-cutting piercing pencil point and an opening 53 for providing feedback. The spinal catheter is slidably mounted on the needle and shorter than the needle in order for exposing the pencil tip of the needle. The first and second attachment is considered to be the structures which provides the friction fit. The force absorbing structure is considered the nose 65 of the catheter. Zohmann further discloses a central stylet 30 mounted in the needle.

Claims 5,21 lack an inventive step under PCT Article 33(3) as being obvious over Zohmann (6,558,353) in view of Kreuzer et al. (US 5,116,323).

Zohmann discloses the invention as substantially claimed. See above. However, Zohmann is silent to the connections being a luer lock. Kreuzer et al. discloses a catheter assembly having luer lock connections between the catheter and needle structures. It would have been obvious to one of ordinary skill in the connector art to modify the friction fit connection of Zohmann with a luer lock connector as taught by Kreuzer et al. in order to provide an improved and more secured connection between the catheter and the needle.

Claims 7, 22, 26 lack an inventive step under PCT Article 33(3) as being obvious over Zohmann (6,558,353) in view of Edwards et al. (US 5,370,624).

Zohmann discloses the invention as substantially claimed. See above. However, Zohmann is silent to the catheter hub having a luer lock connector for attachment to a medical fluid transfer equipment or that the connection is generally perpendicular to the direction of the catheter insertion. Edwards et al. discloses a catheter having a hub which has a perpendicular port for connection to medical transfer equipment. See element 12 and 20 of the Edwards et al. reference. It would have been obvious to one of ordinary skill in the connection art to modify the hub of Zohmann to include an additional port on the side port as taught by Edwards et al. in order to provide a selectively accessible passage that is capable of being activated or deactivated to allow fluid to be infused through the sideport.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US04/35411

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Claims 6, 10-11, 13, 19 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a spinal catheter in combination with all the elements and further including a second material at the distal tip for radial reinforcement.

Claims 1-26 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.